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| WILSON SONSINI GOODRICH & ROSATI | | | AZARIAN, SEYED H | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) |
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| | 10/062,627 | DECHARMS, R. CHRISTOPHER |
| Office Action Summary | Examiner | Art Unit |
| | Seyed Azarian | 2625 |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | orrespondence address |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be ting within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. CD (35 U.S.C. § 133). |
| Status | | |
| 1) Responsive to communication(s) filed on 30 Ja 2a) This action is FINAL. 2b) This 3) Since this application is in condition for alloware closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | |
| · | .x parte Quayle, 1905 C.D. 11, 4. | J3 O.G. 213. |
| Disposition of Claims | | |
| 4) Claim(s) 1-26 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) Claim(s) is/are allowed. 6) Claim(s) 1-26 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/o | vn from consideration. | |
| Application Papers | | |
| 9)☐ The specification is objected to by the Examine 10)☒ The drawing(s) filed on 30 January 2002 is/are: Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11)☐ The oath or declaration is objected to by the Ex | a)⊠ accepted or b)⊡ objected drawing(s) be held in abeyance. Section is required if the drawing(s) is ob | e 37 CFR 1.85(a). ejected to. See 37 CFR 1.121(d). |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Applicati ity documents have been receive u (PCT Rule 17.2(a)). | ion No ed in this National Stage |
| Attachment(s) | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal P 6) Other: | |

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DETAILED ACTION

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claim 1-12, 14-17 and 19-26, are rejected under 35 U.S.C. 103(a) as being unpatentable over "J.T. Voyvodic, "Real-time fMRI Paradigm Control, Physiology, and Behavior Combine with Near Real-Time Statistical Analysis", in view of Toni et al, "The Time Course Of Changes Motor Sequence Learning: A Whole-Brain fMRI Study".

Regarding claim 1, Voyvodic discloses computer executable software and device for guiding brain activity training comprising (page 105, column 2, paragraph 3, fMRI analysis quality does not need be compromised for speed, by using efficient software and speed of current computer processors can accurately control and monitor a wide range of physiological and behavioral variables and provide immediate statistical analysis of brain activation);

logic which takes data corresponding to activity measurements of one or more internal voxels of a brain and determines one or more members of the group consisting of (see Fig. 3 and 4, also, page 93, column 1, paragraph 4, through column 2, paragraph 2, fScan (logic) was used for a variety of analysis tasks, due to its flexibility in accepting data input, timing of tasks

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conditions, behavioral responses, physiological wave form recordings, it also provides data processing one voxel time course at a time);

- a) what next stimulus to communicate to the subject (page 94, column 1, paragraph 4, through column 2, paragraph 2, paradigms were programmed to begin tasks automatically as soon as scan had begun, first subjects watched a central fixation crosshair on black background, around which appeared moving white dots);
- c) when a subject is to be exposed to a next stimulus, (page 94, column 1, paragraph 4, second paradigm subjects fixated on a central crosshair)'
- d) when the subject is to perform a next behavior, (page 94, column 1, paragraph 4, through column 2, paragraph 1, third paradigm, subjects read simple sentences and answered true/false questions);
- e) one or more activity metrics computed from the measured activity, (page 94, column 2, paragraph 2, recorded heartbeat, respiration, and recording behavioral sampling at 100Hz (metrics));
- f) a spatial pattern computed from the measured activity, (page 98, column 2, paragraph 3, each voxel time course was sorted by six different parameters resulting in maps (patterns) indicating spatial distribution);
- g) a location of a region of interest computed from the measured activity, (page 98, column 2, paragraph 3, the task reference produced regression maps with localized sites);
- h) performance targets that a subject is to achieve computed from the measured activity, (page 99, column 2, and paragraph 1, t test maps that were correlated with the task conditions);

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I) a performance measure of a subject's success computed from the measured activity, (see Fig. 1);

j) a subject's position relative to an activity measurement instrument; (page 101, column 2, paragraph 3, analysis software (fScan) combined with fMRI and more comprehensive statistical post processing, the real-time processing is cable of head motion measurements (position);

and logic for communicating information based on the determinations to the subject in substantially real time relative to when the activity is measured (page 93, column 1, paragraph 4 through column 2, paragraph 1, fScan for real-time processing reads data directly from scanner or from saved files, it could accept time course input data, such as timing of task conditions, subjects behavioral response, physiological wave form recordings).

However, Voyvodic discloses a method of using fMRI and computer executable software for training and mapping brain activity, but does not explicitly state "what next behavior to instruct the subject to perform (read text instruction while performing the tasks)". On the other hand Toni in the same field of fMRI brain studies and training teaches that when given tasks the subjects can read text message, "GOOD" on a screen when task is completed correctly, at the end of baseline block, another message, "GET READY" appeared on the screen (see page 51, column 2, paragraphs 3-4).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Voyvodic invention according to the teaching of Toni because it provides the text instruction screen in Voyvodic as taught be Toni in order for the subject to read

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text instruction during task, which can easily be implemented to the software storage modules of an integrated surveillance system).

Regarding claim 2, Voyvodic discloses the software and device according to claim 1 wherein measuring brain activity is performed by fMRI. (page 92, column 1, paragraph 3, fMRI reliability that combines flexible software tools for accurate real-time paradigm control and online fMRI analysis).

Regarding claim 3, Voyvodic discloses the software and device according to claim 1 wherein the determinations are made in less than 10 seconds relative to when the activity is measured (page 93, column 1, first paragraph the real-time processor is its ability to specify the exact time (to within 20 us), at which each operation is to be executed, also Fig. 1, page 95, first paragraph).

Regarding claim 4, Voyvodic discloses the software and device according to claim 1 wherein the determinations are made in less than 1 second relative to when the activity is measured (page 93, column 1, first paragraph the real-time processor is its ability to specify the exact time (to within 20 us), at which each operation is to be executed).

Regarding claim 5, Voyvodic discloses the software and device according to claim 1 wherein the determinations are made in less than 0.5 second relative to when the activity is measured (page 93, column 1, first paragraph the real-time processor is its ability to specify the exact time (to within 20 us), at which each operation is to be executed).

Regarding claim 6, Voyvodic discloses the software and device according to claim 1 wherein the information is determined while the instrument used for measurement remains positioned about the subject (page 105, column 2, paragraph 3, fMRI analysis quality does not

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need be compromised for speed, by using efficient software and speed of current computer processors can accurately control and monitor a wide range of physiological and behavioral variables and provide immediate statistical analysis of brain activation).

Regarding claim 7, Voyvodic discloses the software and device according to claim 1 wherein the activity measurements are made using a device capable of taking measurements from one or more internal voxels without substantial contamination of the measurements by activity from regions intervening between the internal voxels being measured and where the measurement apparatus collects the data (see Fig. 3 and 4, also, page 93, column 1, paragraph 4, thru column 2, paragraph 2, fScan (logic) was used for a variety of analysis tasks, due to its flexibility in accepting data input, timing of tasks conditions, behavioral responses, physiological wave form recordings, it also provides data processing one voxel time course at a time).

Regarding claim 8, Voyvodic discloses the software and device according to claim 1 wherein measurements are made from at least 100 separate internal voxels, and these measurements are made at a rate of at least once every five seconds (page 96, last paragraph Fig. 3, show amount of voxels).

Regarding claim 9, Voyvodic discloses the software and device according to claim 1 wherein measurements are made from a set of separate internal voxels corresponding to a scan volume including the entire brain (see clime 8, also Fig. 3, show displacement and separation of each nine slice voxels).

Regarding claim 10, Voyvodic discloses the software and device according to claim 1 wherein the size of the internal voxels have a total three dimensional volume of 5 times 5 times 5 cm or less (see Fig. 3 and 5, $3.2 \times 3.2 \times 3$ mm (refer to voxel size and less than $5 \times 5 \times 5$ cm)).

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Regarding claim 11, Voyvodic discloses the software and device according to claim 1 wherein the size of the internal voxels have a total three dimensional volume of 1.times.1.times.1 cm or less (see Fig. 3 and 5, 3.2 x 3.2 x 3 mm (refer to voxel size and less than 5 x 5 x 5 cm)).

Regarding claim 12, Voyvodic discloses the software and device according to claim 1 wherein the software further comprises logic for selecting one or more of the internal voxels to correspond to a region of interest for the subject and using the selected internal voxels of the region of interest to make the one or more determinations (page 98, column 2, paragraph 3, the task reference produced regression maps with localized sites).

Regarding claim 14 and 15, Voyvodic discloses the software and device according to claim 1 wherein the information communicated is "an instruction" to the subject (see claim 1, Also page 92, column 1, second paragraph, designing software for real-time fMRI and monitoring throughout each scan).

Regarding claim 17, Voyvodic discloses the software and device according to claim 14 wherein the instruction is determined by computer executable logic (page 92, column 1, second paragraph, designing software for real-time fMRI and monitoring throughout each scan).

Regarding claim 21, Voyvodic discloses a method according to claim 20 wherein measuring brain activity is performed by fMRI (page 1, paragraph first, refer to fMRI).

Regarding claims 19 and 22, arguments analogous to those presented for claims 8 and 14 are applicable.

Regarding claim 16, arguments analogous to those presented for claim 15 are applicable.

Regarding claims 16, 20 and 23-26, arguments analogous to those presented for claims 1 and 17 are applicable.

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3. Claim 13, is rejected under 35 U.S.C. 103(a) as being unpatentable over "J.T. Voyvodic, "Real-time fMRI Paradigm Control, Physiology, and Behavior Combine with Near Real-Time Statistical Analysis", in view of Toni et al, "The Time Course Of Changes Motor Sequence Learning: A Whole-Brain fMRI Study", as applied to claims above and further in view of Merzenich (U.S. 6,234,979).

Regarding claim 13, Voyvodic discloses the software and device according to claim 1 wherein the information is communicated by a manner selected from the group consisting of providing audio to the subject, displaying an image to the subject (page 101, column 2, second paragraph, simultaneously present audio and /or video stimuli, record "behavioral and physiological responses, also page 105, column 1, second paragraph refer to display the results through evaluation).

However regarding claim 13, neither Voyvodic nor Toni explicitly state "providing tactile stimuli to the subject and providing a smell to the subject". On the other hand Merzenich, in the same field of fMRI brain studies and training teaches super group can also occurs in any one of the sensory domains, hearing, tactile, smell, taste, vision (column 5, lines 51-62).

Therefore it would have been obvious to a person of ordinary skill in the art at time the invention was made, to modify Voyvodic and Toni invention according to the teachings of Merzenich because it provides a method for implementing a training regimen which alleviates exaggerated sensory, which fully satisfies the requirements of claim.

4. Claim 18, is rejected under 35 U.S.C. 103(a) as being unpatentable over "J.T. Voyvodic, "Real-time fMRI Paradigm Control, Physiology, and Behavior Combine with Near Real-Time Statistical Analysis", in view of Toni et al, "The Time Course Of Changes Motor Sequence

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Learning: A Whole-Brain fMRI Study", as applied to claims above and further in view of Biswal et al (U.S. 6, 477,399).

Regarding claim 18, neither Voyvodic nor Toni explicitly state, "instruction communication is selected from a set of instructions stored in memory". On the other hand Biswal in the same field of fMRI brain studies and training teaches (see Fig. 7, element 326, processing block 326) that correlation value is stored in a table, as determined at decision block (instruction).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Voyvodic and Toni invention according to the teaching of Biswal because it provides instruction storage ,which can easily be implemented to the software storage such as fMRI system.

Other prior art cited

- 5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
 - U.S. patent (6,370,416) to Rosenfeld is cited for FMRI signal processing.
- U.S. patent (6,275,723) to Ferris et al is cited for method and apparatus for performing neuroimaging.
- U.S. patent (5,603,322) to Jesmanowicz et al is cited for time course MRI imaging of brain function.
- U.S. patent (6,463,315) to Klingberg et al is cited for analysis of cerebral white matter for prognosis and diagnosis of neurological disorders.

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U.S. patent (6,477,399) to Biswal et al is cited for method for determining the reliability of FMRI parameters.

U.S. patent (6,517,812) to Breiter et al is cited for inhibition of psychostimulant-induced and nicotine craving.

Contact Information

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Seyed Azarian whose telephone number is (571) 272-7443. The examiner can normally be reached on Monday through Thursday from 6:00 a.m. to 7:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta, can be reached at (571) 272-7453. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.

Status information about the PAIR system, see http:// pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Seyed Azarian
Patent Examiner
Group Art Unit 2625
April 11, 2005

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